Human-AI Collaboration Increases Efficiency in Regulatory Writing: A Study with Takeda Pharmaceutical

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This summary shares final findings from a collaborative study led by Weave Bio and Takeda Pharmaceutical, now available as a preprint (arXiv:2509.09738). The study compared AI-assisted content generation with traditional authoring using two previously submitted INDs, focusing on both preparation time and content quality.

The study was conducted using Weave's AutoIND, which has since been incorporated into the Weave Platform. It examined IND sections 2.6.2 (Pharmacology), 2.6.4 (Pharmacokinetics), and 2.6.6 (Toxicology)-areas known for their analytical depth and narrative complexity. The use of AutoIND reduced first-draft preparation time by ~97% (from ~100 hours to under 4) while delivering quality scores comparable to human-written content, with no critical regulatory errors observed.

The results demonstrate that AI can significantly accelerate regulatory writing, while expert oversight remains essential for refinement, strategic judgment, and alignment with organizational preferences.

Read the full study here: https://arxiv.org/abs/2509.09738

Productivity at Scale: Time Impact

At the start of the study, the pharma team shared that drafting similar IND content typically takes ~100 FTE hours. To measure comparable performance in The Weave Platform, preparation time was tracked for two dedicated pharma users, and content was prepared in The Weave Platform in under 4 hours-resulting in ~97% time savings.
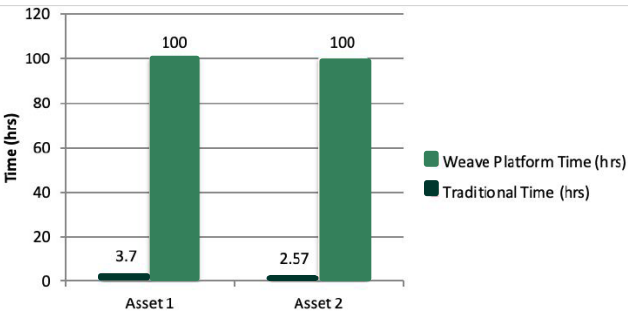

Quality Scoring Framework

A Quality Scoring Framework was used to compare the first draft of AI-assisted content from The Weave Platform to the final draft of traditionally prepared content. Six key focus areas were assessed:

- Correctness
- Completeness
- Redundancy
- Conciseness
- Clarity
- Emphasis

Each area was rated by an unbiased evaluator on a scale of 0 to 3, with 3 representing the highest possible quality score. The scores were then aggregated to calculate an overall quality percentage for each drafted IND summary. This framework enabled a structured, side-by-side comparison of draft quality across both methods.
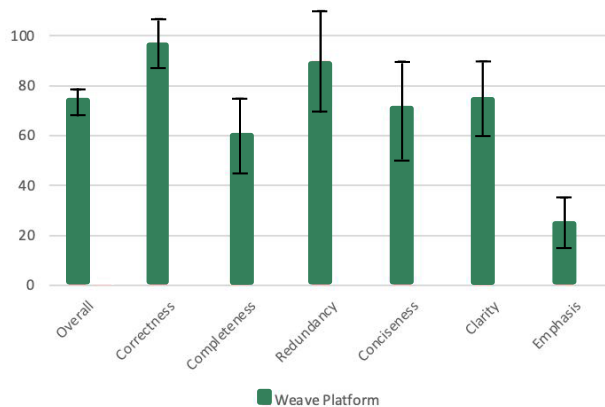
Content quality results, when aggregated across the six focus areas for the two fully scored study summaries, were as follows:

- Asset 1: The Weave Platform-generated first draft content received an overall score of 89.5%.
- Asset 2: The Weave Platform-generated first draft content received an overall score of 66.7%.

Across both IND studies, clear patterns emerged-revealing where AI-assisted drafting with The Weave Platform consistently performs well and where human input plays a critical role in shaping high-quality regulatory content. Examples include:

Focus Area: Correctness

In The Weave Platform, AI-assisted content consistently scores high where it matters most: accuracy and faithfulness to source documents.

Focus Area: Completeness

When prompted correctly in the AutoIND template, requested information is consistently included. For example, asking to "describe all endpoints" results in all endpoints being described.

Focus Areas: Redundancy & Clarity

AI-assisted content in The Weave Platform can be too wordy or too brief if not guided properly, resulting in inconsistent scores.

Focus Area: Conciseness

Structure, tone, and level of detail are highly consistent in AI-assisted content within The Weave Platform, leading to a high score.

Focus Area: Emphasis

AI-assisted content in The Weave Platform struggles with emphasis-human judgment remains essential to ensure a clear, focused narrative.

AI's Growing Role in the Regulatory Lifecycle

These findings highlight the value of combining AI-native tools with human expertise. In the study, The Weave Platform streamlined the drafting process and gave teams flexibility to refine content in real time-reducing manual effort and accelerating review cycles without compromising quality.

While AI boosts speed and consistency, expert oversight remains essential to account for organizational context and nuance. Together, a robust AI platform guided by expert users creates a more efficient, adaptable model for regulatory content development.